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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,121	10/04/2000	Cynthia K. French	107-206-C	7802

7590 05/20/2002

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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,121	FRENCH ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39,40,42-45,48-50 and 56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39,40,42-45,48-50 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed on February 11, 2002 (Paper No. 9) to the restriction requirement of 12-11-01 has been received. Applicant has elected Group I, without traverse.

Claims 41, 46-47, and 51-55 were cancelled.

Claims 39-40, 42-45, 48-50, and 56 are pending and are currently under examination.

Inventorship

In view of the papers filed 9-25-01, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by deleting Patrick A. Schneider and adding A. Said El Shami.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claim Objections

Claim 48 is objected to for including claims drawn to "antisense sequences" as such claims are drawn to a non-elected invention (see Paper No. 8, page 2). Applicant is requested to

cancel those portions of Claim 48 drawn to antisense sequences which were originally restricted as independent and or distinct from the presently claimed invention.

Specification

The specification is objected to for the following reason: The specification on page 1 should be amended/updated to reflect the present priority status of the application to indicate that application No. 09/036,315, is now U.S. Patent No. 6,218,523.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48-49 are rejected as vague for reciting "a recombinant polynucleotide comprising an expression control sequence operably linked to a nucleotide sequence encoding" a "polynucleotide probe or primer" or "inhibitory polynucleotide" in Claim 48 as it is unclear how a nucleotide sequence can encode anything other than a polypeptide sequence.

Claims 48-49 are rejected as vague and indefinite for reciting the term "Repro-PC-1.0" as the sole means of identifying the claimed molecule. The use of laboratory designations only to

identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify Repro-PC.1.0, for example, by SEQ ID NO.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 43,45,48-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier *et al.* (GeneBank Database, Accession No. AA081755, October 1996).

Hillier *et al.* teach a polynucleotide comprising at least 40 consecutive nucleotides of SEQ ID NO:1 (attached at end of action). Such a polynucleotide is also a probe or primer of at least 40 nucleotides that would inherently hybridize to a nucleotide sequence selected from Repro-PC-1.0 cDNA SEQ ID NO:1 or its complement. Hillier *et al.* further teach that said probe of at least 40 nucleotides comprises a label since the vector comprising the nucleotides is cloned within pBluescript, a vector comprising a label for chloramphenical resistance. Hillier *et al.* further teach a recombinant cell comprising the recombinant polynucleotide of at least 40 nucleotides wherein the cell is neuroepithelial cells.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43,45, and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara *et al.* (WO/9514772, sequence listing, June 1, 1995).

Matsubara *et al.* teach a polynucleotide comprising at least 40 consecutive nucleotides of SEQ ID NO:1. (attached at end of action). Such a polynucleotide is also a probe or primer of at least 40 nucleotides that would inherently hybridize to a nucleotide sequence selected from Repro-PC-1.0 cDNA SEQ ID NO:1 or its complement. Matsubara further teach that said probe of at least 40 nucleotides comprises a label- poly(T). Matsubara *et al.* further teach a recombinant cell comprising the polynucleotides in that the polynucleotides were obtained from 3'-directed cDNA libraries prepared from various human tissues. Such human tissues would inherently comprise recombinant cells.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 40 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6,218,523 ('523). This is a double patenting rejection. Claim 40, drawn to a polynucleotide wherein the nucleotide sequence encodes native Repro-PC-1.0

polypeptide (SEQ ID NO:2) appears equal in scope to the patented invention of a recombinant polynucleotide comprising a nucleotide sequence encoding a polypeptide whose amino acid sequence is identical to SEQ ID NO:2 (Claim 3 of the '523 Patent). The only difference appears to be the inclusion of the word "native" in Claim 40. However, the specification teaches (page 29, line 10) that Repro-PC-1.0 polypeptide refers to "native" Repro-PC-1.0, the polypeptide whose amino acid sequence is the amino acid sequence of SEQ ID NO:2. Thus, the conflicting claims are coextensive in scope.

Claim 40 is directed to the same invention as that of claim 3 of commonly assigned US Patent 6,218,523. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-40, 42-45, 48-50, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent No. 6,218523. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Claims 40 and 48 are broadly drawn to a nucleotide sequence or a recombinant polynucleotide comprising an expression control sequence operably linked to a nucleotide sequence encoding the polypeptide of SEQ ID NO:2 or Repro-PC-1.0. Although not identical, they are not patentably distinct from Claim 3 of the '523 patent since the inclusion of "expression control sequences operably linked" is inherent to transcriptional regulation, and merely represents an obvious variation over the encoded product as claimed in Claim 3 of '523.

Claims 43-45, and 48 are broadly drawn to a polynucleotide probe or primer wherein said probe or primer is 40 nucleotides in length, is identical to SEQ ID NO:1, or is identical to the complement of SEQ ID NO:1 and hybridizes to SEQ ID NO:1 or its complement. Although not identical, Claims 43-45 and 48 are not patentably distinct from Claims 4-5 which also claim probes or primers that are complementary or identical to the nucleotide sequence of SEQ ID NO;1 or its complement and further include that the probe comprise a label.

Claim 49, drawn to a polynucleotide comprising at least 40 consecutive nucleotides of SEQ ID NO:1 is not patentably distinct from Claim 2 of the '523 patent which is drawn to a recombinant polynucleotide comprising nucleotides 151-1425 of SEQ ID NO:1 since the patented claims include at least 40 consecutive nucleotides of SEQ ID NO:1.

Claim 50, drawn to a recombinant cell comprising a recombinant polynucleotide is also rejected under obvious-type double patenting over claim 3 of the '523 patent, since it would be obvious to any one of ordinary skill to include a host cell for the purpose of recombinant expression of the polynucleotide encoding a Repro-PC-1.0 polypeptide (SEQ ID NO:2).

Claims 39, 42, and 56, drawn to polynucleotide sequences encoding various amino acid segments of SEQ ID NO:2, are obvious variations over Claim 3 in the '523 patent since Claim 3 is drawn to a polynucleotide encoding the complete amino acid sequence of SEQ ID NO:2. The various fragments are mere coextensive variations in that it would obvious to make antibodies against any portion of the complete product and to identify which portions are diagnostically significant in detecting SEQ ID NO:2.

Claims 39-40, 42-45, 48-50, 56 are directed to an invention not patentably distinct from claims 2-5 of commonly assigned US Patent No. 6218523 for the reasons recited above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6218523, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the

invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 19, 2002